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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/416,902	10/13/1999	JOHN MCCAFFERTY	05569.0004.DVUS06	6750

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HOWREY LLP  
C/O IP DOCKETING DEPARTMENT  
2941 FAIRVIEW PARK DR, SUITE 200  
FALLS CHURCH, VA 22042-2924

EXAMINER
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STEELE, AMBER D

ART UNIT	PAPER NUMBER
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1639

MAIL DATE	DELIVERY MODE
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08/16/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

09/416,902

**Applicant(s)**

MCCAFFERTY ET AL.

**Examiner**

Amber D. Steele

**Art Unit**

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 3/6/07; 4/2/07; 6/6/07.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte*, Quayle, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 44, 47, 48 and 53-62 is/are pending in the application.
- 4a) Of the above claim(s) 53-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 44, 47, 48, 61 and 62 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☒ Certified copies of the priority documents have been received in Application No. 07/971,857.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 6, 2007 has been entered.

### ***Status of the Claims***

2. New claims 61-62 have been added and claims 46 and 51-52 have been canceled by the amendment filed on November 30, 2005.

The amendment to the claims received on April 2, 2007 amended claim 44 and canceled claim 45.

The supplemental amendment received on June 6, 2007 amended claim 44.

Claims 44, 47-48, and 53-62 are currently pending.

Claims 44, 47-48, and 61-62 are currently under consideration.

### ***Election/Restrictions***

3. Applicant's election of group I, claims 44-52 in the reply filed on March 15, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

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4. Claims 53-60 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Election was made **without** traverse in the reply filed on March 15, 2004.

***Priority***

5. This application is a divisional of 08/484,893 filed June 7, 1995 (now U.S. Patent 6,172,197), which is continuation of 07/971,857 filed January 8, 1993 (now U.S. Patent 5,969,108), which is a continuation of PCT/GB91/01134 filed July 10, 1991.

6. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d) for UK 9015198.6 filed July 10, 1990; UK 9022845.3 filed October 19, 1990; and UK 9024503.6 filed November 12, 1990. The certified copies have been filed in parent Application No. 07/971,857, filed on January 8, 1993.

***Invention as Claimed***

7. A method of obtaining a member of a specific binding pair the method comprising: (a) providing a library of in vitro mutagenized nucleic acid from an existing antibody coding sequence, (b) producing a library of filamentous bacteriophage particles displaying a population of specific binding pair members which comprise a binding domain of an immunoglobulin each particle containing nucleic acid from the library of in vitro mutagenized nucleic acid from an existing antibody coding sequence, (c) contacting the library of filamentous bacteriophage particles with a desired epitope, and (d) separating particles displaying specific binding pair members comprising a binding domain which binds to said epitope wherein the specific binding pair members are Fabs.

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### **Withdrawn Claim Rejections**

8. The rejection of claims 44 and 47-48 under 35 U.S.C. 102(e) as being anticipated by US Patent 5,837,500 (Ladner et al.) (filing date 9/2/1998) is withdrawn in view of the claim amendment limiting the specific binding pair members to Fabs. In addition, it is noted that Ladner et al. only disclose methods of phage display for proteins smaller than Fab.

9. The rejection of claims 44, 46-48, and 51-52 under 35 U.S.C. 102(a or e) as being anticipated by US 2002/0150881 A1 now US Patent 6,979,538 (Ladner et al) (effective filing date 9/2/1988) is withdrawn in view of the claim amendment limiting the specific binding pair members to Fabs. In addition, it is noted that Ladner et al. only disclose methods of phage display for proteins smaller than Fab.

### **New Rejection Necessitated by Amendment**

#### ***Claim Rejections - 35 USC § 103***

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claims 44, 47, 48, 61, and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huse et al. Science 246(4935): 1275-1281, 1989 and Dower et al. U.S. Patent 5,427,908 filed May 1, 1990.

For present claim 44, Huse et al. teach methods of producing, screening, and isolating Fab comprising providing a combinatorial antibody library (i.e. in vitro mutagenized nucleic acid

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from an existing antibody coding sequence), producing lambda phage particles displaying Fab, contacting the Fab phage displayed library with antigen, and separation via nitrocellulose lifts (please refer to entire reference particularly pages 1276-1279).

For present claims 47-48 and 61-62, Huse et al. teach obtaining a phage displayed Fab, performing saturation mutagenesis on the Fab, rescreening for binding (i.e. phage display new Fab, contact with antigen, separation), and/or recombining the VH or VL with the VL or VH libraries, respectively (please refer to entire reference particularly page 1280, right column).

However, Huse et al. does not teach filamentous bacteriophage.

For present claims 44, 47-48, and 61-62, Dower et al. teach filamentous bacteriophage (please refer to the entire specification particularly columns 1-2 summary of the invention section, claim 1).

The combination of the method taught by Huse et al. with the filamentous bacteriophage taught by Dower et al. would have been obvious because the substitution of one known element (i.e. lambda phage) for another (i.e. filamentous phage) would have been conventional to one of ordinary skill in the art. In addition, the specific phage utilized would have been an experimental design choice based on the desired outcome, future manipulations/experiments, and/or resources available.

#### ***Future Communications***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amber D. Steele whose telephone number is 571-272-5538. The examiner can normally be reached on Monday through Friday 9:00AM-5:00PM.

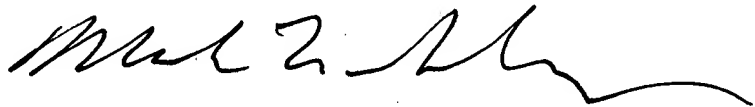
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Doug Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ADS

August 6, 2007

A handwritten signature in black ink, appearing to read 'Mark L. Shibuya', with a long horizontal flourish extending to the right.

MARK L. SHIBUYA  
PRIMARY EXAMINER